Complete Summary

GUIDELINE TITLE

Prevention of perinatal group B streptococcal disease. Revised guidelines from CDC.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Prevention of perinatal group B streptococcal disease: revised guidelines from CDC. MMWR Recomm Rep 2002 Aug 16;51(RR-11):1-22. [142 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Perinatal group B streptococcal disease

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Infectious Diseases
Obstetrics and Gynecology
Pathology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Clinical Laboratory Personnel

Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To update recommendations and guidelines for the prevention of perinatal group B streptococcal (GBS) disease

TARGET POPULATION

- Pregnant women
- Infants born to mothers who received intrapartum group B streptococcal prophylaxis

INTERVENTIONS AND PRACTICES CONSIDERED

1. Prenatal culture-based screening for anogenital group B streptococcal (GBS) colonization
2. Intrapartum chemoprophylaxis with:
    - Intravenous (IV) penicillin G or IV ampicillin;
    - IV cefazolin for women allergic to penicillin but not at high risk for anaphylaxis;
    - IV clindamycin or IV erythromycin for women allergic to penicillin and at high risk for anaphylaxis;
    - IV vancomycin for women allergic to penicillin with GBS resistant to clindamycin or erythromycin or susceptibility unknown
3. Procedures for:
    - Collecting and processing clinical specimens for culture of group B streptococcus
    - Clindamycin and erythromycin disk susceptibility testing of isolates for penicillin-allergic patients

Note: Rapid tests to detect GBS colonization status and vaccines to prevent GBS disease were discussed as future prevention technology; however, no recommendations were offered.

MAJOR OUTCOMES CONSIDERED

- Impact of prevention efforts on incidence of perinatal group B streptococcal (GBS) disease
- Efficacy of intrapartum chemoprophylaxis (i.e., administration of antimicrobial agents after onset of labor or membrane rupture but before delivery) in preventing both early-onset GBS disease and maternal illness resulting from GBS

- Adverse or unintended effects of GBS prevention efforts
- Protective effect of prenatal GBS screening compared with the risk-based approach
- Accuracy of prenatal screening cultures in identifying intrapartum colonization status

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of evidence supporting recommendation

I. Evidence from at least one well-executed randomized, controlled trial or one rigorously designed laboratory-based experimental study that has been replicated by an independent investigator
II. Evidence from at least one well-designed clinical trial without randomization; cohort or case-controlled analytic studies (preferably from more than one center); multiple time-series studies; dramatic results from uncontrolled studies; or some evidence from laboratory experiments
III. Evidence from opinions of respected authorities based on clinical or laboratory experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of recommendations

A. Strong evidence for efficacy and substantial clinical benefit (Strongly recommended)
B. Strong or moderate evidence for efficacy, but only limited clinical benefit (Generally recommended)
C. Insufficient evidence for efficacy; or efficacy does not outweigh possible adverse consequences. (Optional)
D. Moderate evidence against efficacy or for adverse outcome. (Generally not recommended)
E. Strong evidence against efficacy or for adverse outcome. (Never recommended)

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the quality of evidence (I-III) and strength of recommendations (A-E) are provided at the end of the "Major Recommendations" field.

Obstetric-care practitioners, in conjunction with supporting laboratories and labor and delivery facilities, should adopt the following strategy for the prevention of perinatal group B streptococcal (GBS) disease based on prenatal screening for GBS colonization. The risk-based approach is no longer an acceptable alternative except for circumstances in which screening results are not available before delivery (AII).

- All pregnant women should be screened at 35--37 weeks' gestation for vaginal and rectal GBS colonization (AII). At the time of labor or rupture of membranes, intrapartum chemoprophylaxis should be given to all pregnant women identified as GBS carriers (AII). Colonization during a previous pregnancy is not an indication for intrapartum prophylaxis in subsequent

deliveries. Screening to detect GBS colonization in each pregnancy will determine the need for prophylaxis in that pregnancy.

- Women with GBS isolated from the urine in any concentration (e.g., 10^3) during their current pregnancy should receive intrapartum chemoprophylaxis because such women usually are heavily colonized with GBS and are at increased risk of delivering an infant with early-onset GBS disease (BII). Labels on urine specimens from prenatal patients should clearly state the patient's pregnancy status to assist laboratory processing and reporting of results. Prenatal culture-based screening at 35--37 weeks' gestation is not necessary for women with GBS bacteriuria. Women with symptomatic or asymptomatic GBS urinary tract infection detected during pregnancy should be treated according to current standards of care for urinary tract infection during pregnancy.
- Women who have previously given birth to an infant with invasive GBS disease should receive intrapartum chemoprophylaxis; prenatal culture-based screening is not necessary for these women (BII).
- If the result of GBS culture is not known at the onset of labor, intrapartum chemoprophylaxis should be administered to women with any of the following risk factors: gestation <37 weeks, duration of membrane rupture $\geq$18 hours, or a temperature of $\geq$100.4Âº F ($\geq$38.0ÂºC) (AII). Women with known negative results from vaginal and rectal GBS screening cultures within 5 weeks of delivery do not require prophylaxis to prevent GBS disease even if any of the intrapartum risk factors develop.
- Women with threatened preterm (<37 weeks' gestation) delivery should be assessed for need for intrapartum prophylaxis to prevent perinatal GBS disease. An algorithm for management of women with threatened preterm delivery is provided in the original guideline document. Other management approaches, developed by individual physicians or institutions, may be appropriate (CIII).
- Culture techniques that maximize the likelihood of GBS recovery are required for prenatal screening (see Box 1 in the original guideline document). Collection of specimens for culture may be conducted in the outpatient clinic setting by either the patient, with appropriate instruction, or health-care provider (BII). This involves swabbing the lower vagina and rectum (i.e., through the anal sphincter). Because lower vaginal as opposed to cervical cultures are recommended, cultures should not be collected by speculum examination. Specimens should be placed in a nonnutritive transport medium (e.g., Amies or Stuart's without charcoal). Specimen labels should clearly identify that specimens are for group B streptococcal culture. If susceptibility testing is ordered for penicillin-allergic women (see Box 2 in the original guideline document), specimen labels should also identify the patient as penicillin allergic and should specify that if GBS is isolated, it should be tested for susceptibility to clindamycin and erythromycin. Specimens should be inoculated into a selective broth medium (examples of appropriate commercially available media include Trans-Vag Broth supplemented with 5% defibrinated sheep blood or LIM broth), incubated overnight, and subcultured onto solid blood agar medium (AII). Methods of testing prenatal isolates from penicillin-allergic women for susceptibility to clindamycin and erythromycin are outlined in Box 1 of the original guideline document. Laboratories should report culture results (positive and negative) and susceptibility testing results to the anticipated site of delivery (when known) and to the health-care provider who ordered the test.

- Health-care providers should inform women of their GBS screening test result and the recommended interventions. In the absence of GBS urinary tract infection, antimicrobial agents should not be used before the intrapartum period to treat GBS colonization. Such treatment is not effective in eliminating carriage or preventing neonatal disease and may cause adverse consequences (DI).
- GBS-colonized women who have a planned cesarean delivery performed before rupture of membranes and onset of labor are at low risk for having an infant with early-onset GBS disease. These women should not routinely receive intrapartum chemoprophylaxis for perinatal GBS disease prevention (CII).
- For intrapartum chemoprophylaxis, the following regimen is recommended for women without penicillin allergy (see Box 2 in the original guideline document): penicillin G, 5 million units intravenously initial dose, then 2.5 million units intravenously every 4 hours until delivery (AII). Because of its narrow spectrum of activity, penicillin is the preferred agent. An alternative regimen is ampicillin, 2 g intravenously initial dose, then 1 g intravenously every 4 hours until delivery (AI). (See Box 2 in the original guideline for details concerning these regimens.)
- Intrapartum chemoprophylaxis for penicillin-allergic women takes into account increasing resistance to clindamycin and erythromycin among GBS isolates (see Box 2 in the original guideline document). During prenatal care, history of penicillin allergy should be assessed to determine whether a patient is at high risk for anaphylaxis, i.e., has a history of immediate hypersensitivity reactions to penicillin (e.g., anaphylaxis, angioedema, or urticaria) or history of asthma or other conditions that would make anaphylaxis more dangerous (CDC, 2002). Women who are not at high risk for anaphylaxis should be given cefazolin, 2 g intravenously initial dose, then 1 g intravenously every 8 hours until delivery (BIII). For women at high risk for anaphylaxis, clindamycin and erythromycin susceptibility testing, if available, should be performed on isolates obtained during GBS prenatal carriage screening. Women with clindamycin- and erythromycin-susceptible isolates should be given either clindamycin, 900 mg intravenously every 8 hours until delivery; OR erythromycin, 500 mg intravenously every 6 hours until delivery. If susceptibility testing is not possible, susceptibility results are not known, or isolates are resistant to erythromycin or clindamycin, the following regimen can be used for women with immediate penicillin hypersensitivity: vancomycin, 1 g intravenously every 12 hours until delivery (CIII).
- Routine use of antimicrobial prophylaxis for newborns whose mothers received intrapartum chemoprophylaxis for GBS infection is not recommended. However, therapeutic use of these agents is appropriate for infants with clinically suspected sepsis. An updated algorithm for management of infants born to mothers who received intrapartum chemoprophylaxis for GBS infection is provided in the original guideline document. This revised algorithm is not an exclusive approach to management; variation that incorporates individual circumstances or institutional preferences may be appropriate (CIII).
- Local and state public health agencies, in conjunction with appropriate groups of hospitals, are encouraged to establish surveillance for early-onset GBS disease and to take other steps to promote perinatal GBS disease prevention and education to reduce the incidence of early-onset GBS disease in their states. Efforts to monitor the emergence of perinatal infections caused by other organisms are also encouraged.

Definitions:

Quality of evidence supporting recommendations

I. Evidence from at least one well-executed randomized, controlled trial or one rigorously designed laboratory-based experimental study that has been replicated by an independent investigator
II. Evidence from at least one well-designed clinical trial without randomization; cohort or case-controlled analytic studies (preferably from more than one center); multiple time-series studies; dramatic results from uncontrolled studies; or some evidence from laboratory experiments
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D. Moderate evidence against efficacy or for adverse outcome. (Generally not recommended)
E. Strong evidence against efficacy or for adverse outcome. (Never recommended)

CLINICAL ALGORITHM(S)

A suggested algorithm is provided for the management of women with threatened preterm delivery. An updated algorithm is provided for management of newborns whose mothers received intrapartum antimicrobial agents for prevention of early-onset group B streptococcal disease or suspected chorioamnionitis.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Increased accuracy of prenatal screening cultures: Numerous studies have documented that the accuracy of prenatal screening cultures in identifying intrapartum colonization status can be enhanced by careful attention to the timing of cultures, the anatomic sites swabbed, and the precise microbiologic methods used for culture and detection of organisms.
- Increased effectiveness of screening: A recent CDC-sponsored multistate study provided the first large-scale direct comparison of the strategies of the risk-based approach versus the screening approach. By incorporating population-based surveillance for early-onset GBS disease into a sample survey of a population of over 600,000 live births, this analysis found that the screening approach was >50% more effective than the risk-based approach at preventing perinatal GBS disease.
- Decreased incidence of perinatal group B streptococcal (GBS): Coinciding with active prevention efforts in the 1990s, the incidence of early-onset disease declined by 70% to 0.5 cases per 1,000 live births in 1999. Projections from active surveillance data for 1999 from the Active Bacterial Core surveillance/Emerging Infections Program Network (ABCs) estimate that intrapartum antibiotics prevented nearly 4,500 early-onset cases and 225 deaths that year. Other countries that have adopted perinatal GBS disease prevention guidelines similar to the United States have seen comparable declines in early-onset disease incidence. Recent estimates of early-onset disease incidence in the United States suggest a slight increase in incidence from 1999 to 2000, consistent with a plateau in the impact of prevention efforts.

  The incidence of invasive GBS infections among pregnant women in the United States declined by 21% from 0.29 per 1,000 live births in 1993 to 0.23 in 1998, suggesting that increased use of intrapartum antibiotics also prevented some cases of maternal GBS amnionitis and endometritis. In contrast, the rate of late-onset disease remained fairly constant throughout the 1990s.

Subgroups Most Likely to Benefit:

- Pregnant women who are colonized with group B streptococcus (GBS) in the genital or rectal areas and who experience either a long duration of membrane rupture, premature delivery, or intrapartum fever
- Pregnant women who previously delivered an infant who had GBS disease.

POTENTIAL HARMS

Potential adverse or unintended effects of group B streptococcal (GBS) prevention efforts that have raised concern include allergic or anaphylactic reactions to agents used for intrapartum antibiotic prophylaxis, emergence of GBS strains resistant to standard therapies, and increasing incidence of serious neonatal infections caused by pathogens other than GBS, including antimicrobial-resistant strains.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Before full implementation of recommended strategies can be expected in all health-care settings, all members of the health-care team will need to improve protocols for isolation and reporting of GBS culture results, to improve information management to ensure communication of screening results, and to educate medical and nursing staff responsible for prenatal and intrapartum care. Within institutions, such efforts may take several months.

Even with ideal implementation, cases of early-onset GBS disease will continue to occur. Tools to help promote prevention and educate parents of infants with early-onset GBS disease are available at www.cdc.gov/groupbstrep. Additional tools available to assist with prevention implementation are available at www.acog.org, http://sales.acog.com, www.aap.org and www.health.state.mn.us/divs/dpc/ades/invbact/strepb.htm. Multiple copies of educational materials published by CDC are available at the Public Health Foundation, 1220 L St., NW Suite 350, Washington, DC 20005, telephone 877-252-1200, or online at www.phf.org.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Prevention of perinatal group B streptococcal disease: revised guidelines from CDC. MMWR Recomm Rep 2002 Aug 16;51(RR-11):1-22. [142 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 May 31 (revised 2002 Aug 16)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American Academy of Pediatrics - Medical Specialty Society
American College of Obstetricians and Gynecologists - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published version (MMWR Recomm Rep 1996 May 31;45(RR-7):1-24).

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML version
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Schrag SJ, Zell ER, Lynfield R, et al. A population-based comparison of strategies to prevent early-onset group B streptococcal disease in neonates. N Engl J Med. 2002 Jul 25;347(4):233-9.
- Schrag SJ, Whitney CG, Schuchat A. Neonatal Group B Streptococcal Disease: How Infection Control Teams Can Contribute to Prevention Efforts. Infect Control Hosp Epidemiol. 2000 Jul;21(7):473-83.
- Group B streptococcal infections frequently asked questions. Atlanta, GA: Centers for Disease Control and Prevention. 1 p.
- Adoption of hospital policies for prevention of perinatal group B streptococcal disease--United States, 1997. MMWR Morb Mortal Wkly Rep. 1998 Aug 21;47(32):665-70.

These and other educational group B streptococcal (GBS) materials are available through the Centers for Disease Control and Prevention (CDC) group B streptococcal disease Web site or by calling the Public Health Foundation, 1-877-252-1200 (toll free) or 301-645-7773 (for international orders), 9:00 a.m. - 4:30 p.m. (Eastern Time), Monday through Friday; Fax: 301- 843-0159; Web site: http://www.phf.org. Electronic order forms are also available at the CDC Web site.

PATIENT RESOURCES

The following are available:

- Group B strep patient brochure. Atlanta, GA: Centers for Disease Control and Prevention, 2000. 2 p.
- Infecciones Por Streptococo Del Grupo B (Group B Strep prenatal brochure). Atlanta, GA: Centers for Disease Control and Prevention, 2000. 2 p.

- Attention Pregnant Women: What You Can Do To Keep Germs from Harming You and Your Baby - Prenatal pamphlet. Atlanta, GA: Centers for Disease Control and Prevention, 2000. 12 p.
- Atención Mujeres Embarazadas: Qué Puede Hacer Para Evitar Que Los Gérmenes La Afecten A Usted Y A Su Bebé - Prenatal pamphlet. Atlanta, GA: Centers for Disease Control and Prevention, 2000. 12 p.

These and other patient-related group B streptococcal (GBS) materials are available through the CDC's group B streptococcal disease Web site or by calling the Public Health Foundation, 1-877-252-1200 (toll free) or 301-645-7773 (for international orders), 9:00 a.m. - 4:30 p.m. (Eastern Time), Monday through Friday; Fax: 301- 843-0159; Website: http://www.phf.org. Electronic order forms are also available at the CDC Web site.

NGC STATUS

This NGC summary was completed by ECRI on January 15, 1998. The information was verified by the guideline developer as of March 1, 1999. The summary was updated by ECRI on October 21, 2002.

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